

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A63B 23/20, A61B 5/0488		A1	(11) International Publication Number: WO 95/22378
			(43) International Publication Date: 24 August 1995 (24.08.95)
(21) International Application Number: PCT/FI95/00087			(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).
(22) International Filing Date: 21 February 1995 (21.02.95)			
(30) Priority Data: 940799 21 February 1994 (21.02.94) FI			
(71)(72) Applicant and Inventor: REMES, Arto [FI/FI]; Visakuja 4 F 18, FIN-70420 Kuopio (FI).			
(74) Agent: PITKÄNEN, Hamu; Savilahdentie 6A, FIN-70210 Kuopio (FI).			
Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. In English translation (filed in Finnish).</i>			
(54) Title: DEVICE FOR TREATMENT OF INCONTINENCE OF URINE			
(57) Abstract			
<p>The invention relates to a device for treating incontinence, which device includes a frame part (1) and a, at least partially tubular, sensor part (2) fastened at an angle in relation to the frame part, having sensors (3) on its sides for measuring the function of the pelvic floor muscles. According to the invention: the sensor part is detachably attached to the frame part (1), which makes it exchangeable regarding to every patient; the sensors (3) are placed on the sides of the sensor-part-tube, on both sides of the center of the side; and the sensors (3) are electrodes which are arranged to measure the muscle activity of the pelvic floor muscles with the help of the electrical signal produced by them.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

DEVICE FOR TREATMENT OF INCONTINENCE OF URINE

The invention relates to a device for treating incontinence, which device includes a frame part and a, at least partially tubular, sensor part fastened at an angle in relation to the frame part, having sensors on its sides for measuring the function of the pelvic floor muscles.

Incontinence means reduction of the ability to restrain urine. The main reason to the problem is the weakening of the pelvic floor muscles and the reduction of their ability to be activated. This may be influenced by a lot of different reasons, for example overweight, psychological reasons and as one reason, the reduction of the restraining ability caused by the delivery of children. It is essential when treating incontinence to restore the muscle strength and the muscle control of the patients pelvic floor muscles. This may be realized through practice or electrical stimulation of the muscles.

These days different kinds of devices exist with which it is possible to exercise the pelvic floor muscles and/or measure their activity. The device is placed in the vagina and when the muscles are contracted the condition of the muscles is elucidated with the help of the data transmitted by the sensors. By repeating the contracting exercises the muscle strength is grown to a level where the problem to hold the urine disappears. With the training made possible with the devices it may be possible to avoid surgery.

Several problems are connected with the known devices. The devices are generally intended for use only in research and laboratory conditions and are not possible to use at home. The devices are often staff-shaped and their use is troublesome. In addition, some devices have a thickening at the end of the staffs which is an inconvenience to the measurements in stand-

CORRECTED

ing and squatting position. When using some devices it is not possible to get them completely clean in spite of the sterilization or exchange of the sensor part, but secretions from the body may transfer from the sensor part to the frame part and stay in cavities in the device. Another problem is the conveniency to handle and the safety to use the device. A disadvantage is also that the device is not easy to adjust to the user.

Devices also exist where a pressure sensor is placed inside a flexible tube which is placed into the vagina. This kind of measurement with pressure is not accurate enough, since it is possible to create pressure in the vagina by squeezing the feet or the muscles in the abdomen or the seat. A disadvantage when using pressure sensors is that it is not possible to discover a situation where the muscles on one side are functioning worse than the muscles on the other side.

The object of the invention is to bring forward a device for treating incontinence with which disadvantages connected to present devices are removed. The object of the invention is especially to bring forward a device which is easy to use both at home and in laboratory conditions and which is safe, reliable and hygienic. Further, the object of the invention is to bring forward a device which is adjustable for different users or which the user may adjust to different values in different phases of the treatment.

The object of the invention is achieved with a device characterized by that described in the claims.

According to the invention the sensor part is detachably attached to the frame part, the sensors are placed on the sides of the sensor-part-tube, on both sides of the center of the side, and the sensors are electrodes which are arranged to

measure the muscle activity of ³the pelvic floor muscles with the help of the electrical signal produced by them. A sensor part according to the invention is a so called disposable part which is exchanged after each patient so that the device is hygienic and safe. When using the device at home it is possible, when the same patient is using the device, to continuously use the sensor part several times in a row. In this case it shall be carefully cleaned after use. The frame part is only exchanged if it is broken. An electronic case is placed inside the frame part, inside which adjustment and functioning organs are placed.

The measurement taking place with the apparatus is preferably based on electromyographic measurement (EMG). The muscle activation of the pelvic floor expressed with a rms-EMG-signal is from a few micro volts to about 50-80 μ V. The electrode plate pairs functioning as sensors register the sum-potential of the contracting muscle and thus the signal accurately describes the activation capacity of the pelvic floor muscles on both sides. The measurement results are collected separately from each side.

A device with a frame part according to the invention is accurately placed in its position in the vagina by placing it in such a position that the frame part extends forward. In this case the sensors are in the desired way at the muscles to be examined or exercised. An additional advantage is that the frame part is spacious enough and can be equipped with the necessary measurement and control electronics and possibly with a displaying device. Still, the device is so small that it can be placed under the trousers.

In the advantageous embodiment of the invention the sensor part is an integrated moulded part. The sensors are situated on the side surface of the tubular part during the moulding, forming a part of the construction. When the sensor part is moulded as an

integrated part no secretions⁴ from the body may enter the sensor part and therethrough continue to the frame part. Thus the device is sufficiently hygienic all the time.

In the second embodiment of the invention a cover belongs to the lower part of the sensor part. The lower surface of the cover is placed on the upper surface of the frame part. The cover protects the frame part so that the frame part does not come into contact with the secretions from the body. The cover is placed at an angle compared with the other part of the sensor part.

The contact connections between the sensors and the frame part are advantageously placed at the frame part. In this way the risk of contamination is small.

In an advantageous additional embodiment of the invention the tube of the sensor part is converging essentially over its whole length 1°-5° against the tip. The tube does not press against the user too much and does not cause pain when using the device. The device may be used in a lying-down, a standing and a squatting position.

In an advantageous embodiment of the invention the sensors are placed on the sides of the tube on both sides of the center of the side symmetrically and at about an 50°-70° angle compared with each other seen from the center of the tube. When the device is accurately placed in its position with the help of the invention, reliable knowledge is acquired of the muscles on both sides separately.

In the following the invention is explained in more detail by referring to the accompanying drawings where

Figure 1 shows an embodiment⁵ of a device according to the invention seen at an angle from below when the sensor part and the frame part are separated from each other

Figure 2 shows another embodiment of a device according to the invention seen at an angle from below when the sensorpart and the frame part are separated from each other

Figure 3 shows a section of a device according to figure 2 and

Figure 4 shows a section A-A according to figure 3.

A device according to the figures includes a frame part 1 and a sensor part 2 detachably attachable to the frame part. A tubular part belongs to the sensor part. The sensors 3 are fastened on the sides of the tubular part. The sensors are ordinary measuring-sensors suitable for the purpose and their number may vary in different embodiments. The sensors are sufficiently long so that they are suitable for different women and are placed at the pelvic floor muscles when the device is in its place. At the lower part of the tubular part are formed a widening-part extending away from and downwards from the tubular part, and a protective edge extending downwards from the widening-part. The widening-part and the protective edge form together the cover 4. The cover is arranged at a blunt angle compared with the rest of the sensor part. The tube is converging about 1°-5° against the tip, which makes it easy to place into the vagina. The material in the sensor is known material which resists disinfection and cleaning.

The sensors 3 are placed on the sides of the tube on both sides of the center in the manner as shown in figure 4. In this embodiment they are at about an 60° angle compared with each other. The sensor part is moulded from homogenous material in such a way that the sensors are first placed in the mould and the plastic part is moulded around them so that the sensors are

integrated in the construction⁶ so that it does not have any cracks or slits.

The tube in the sensor part has in this embodiment a circular cross-section but the cross-section may be elliptical in other embodiments.

In accordance with figure 3 contacting parts 9 are formed at the sides of the tube, with which parts 9 the information given by the sensors is transferred to the frame part 1. An electronic case 5 is placed inside the frame part, which case includes printed circuits and electronic parts for adjustment and use of the device. The frame part is essentially flat, and in the shown embodiments a signalling device and a display unit 8 are placed on its lower surface.

In an embodiment according to figure 1 the device is connected with a cable 10 to a using apparatus which provides it with energy. The display unit and the signalling device may in this case be placed in the frame part or in a separate display unit. In an embodiment according to figure 2 the energy needed to use the device is provided by an accumulator 7 or a battery which is fastened to the frame part in such a way that it reaches into the tube in the frame part. When using an accumulator or a battery the device may be used in home conditions or in a laboratory without an outer energy source. In one embodiment a transmitter unit is connected to the frame part for sending a message without using a cable, and a separate display unit and/or a signalling device which may for example be a device that is to be placed on the wrist belongs to the device.

The signalling device 8 is arranged to be programmed in a manner known in itself to a desired value and to be calibrated to a pre set value. The device has in this case pre set standard levels, for example the levels shown in figures 1 and 2 marked with one and two circles. In the third position it is possible

7
to set suitable individual practice levels for the whole device. The standard levels may then be changed when the practice is progressing and when trying to reach a new practice level.

One embodiment of the invention is a device intended for men. On men the measurement is done in the anal orifice into which the pelvic floor muscles reach. The functional principle of the device stays the same, but the outer dimensions of the sensor is different from those on the models intended for women.)

In an additional embodiment of the invention an alternative for stimulation is incorporated into the device. In this case, necessary devices for emitting electrical pulses to the pelvic floor muscles are attached to the device in a known manner.

The invention is not limited to the shown advantageous embodiments. It may vary within the scope of the inventive idea as stated in the claims.

CLAIMS

1. Device for treating incontinence, which device includes a frame part (1) and a, at least partially tubular, sensor part (2) fastened at an angle in relation to the frame part, having sensors (3) on its sides for measuring the function of the pelvic floor muscles
characterized in that the

- sensorpart (2) is detachably attached to the frame part (1), which makes it exchangeable regarding to every patient.
- the sensors (3) are placed on the sides of the sensor-part-tube, on both sides of the center of the side, and
- the sensors (3) are electrodes, which are arranged to measure the muscle activity of the pelvic floor muscles with the help of the electrical signal produced by them.

2. A device according to claim 1, characterized in that the sensor part (2) is an integrated moulded part. The sensors (3) are situated on the side surface of the tubular part during the moulding, forming a part of the construction.

3. A device according to claim 1 or 2, characterized in that a cover (4) belongs to the lower part of the sensor part (2). The lower surface of the cover is placed on the upper surface of the frame part.

4. A device according to one of claims 1-3, characterized in that the tube of the sensor part is converging essentially over its whole length about 1°-5° against the tip.

9

5. A device according to one of claims 1-4, characterized in that the contact connections (6) between the sensors (3) and the frame part are placed at the frame part.

6. A device according to one of claims 1-5, characterized in that the sensors (3) are placed symmetrically and at about an 50°-70° angle compared with each other.

7. A device according to one of claims 1-6, characterized in that the device includes a battery (7) or a corresponding device, which can be fastened on the frame and placed inside the sensor part.

8. A device according to one of claims 1-7, characterized in that the device includes a signalling device and/or a display unit (8) placed on the lower surface of the frame part.

9. A device according to claim 8, characterized in that the signalling device and/or the display unit (8) are arranged to be programmed to a desired value and to be calibrated to a pre set value.

10. A device according to one of claims 1-9, characterized in that an electronic case is placed inside the frame part, which case includes the adjustment and functioning organs of the device.

FIG. 1

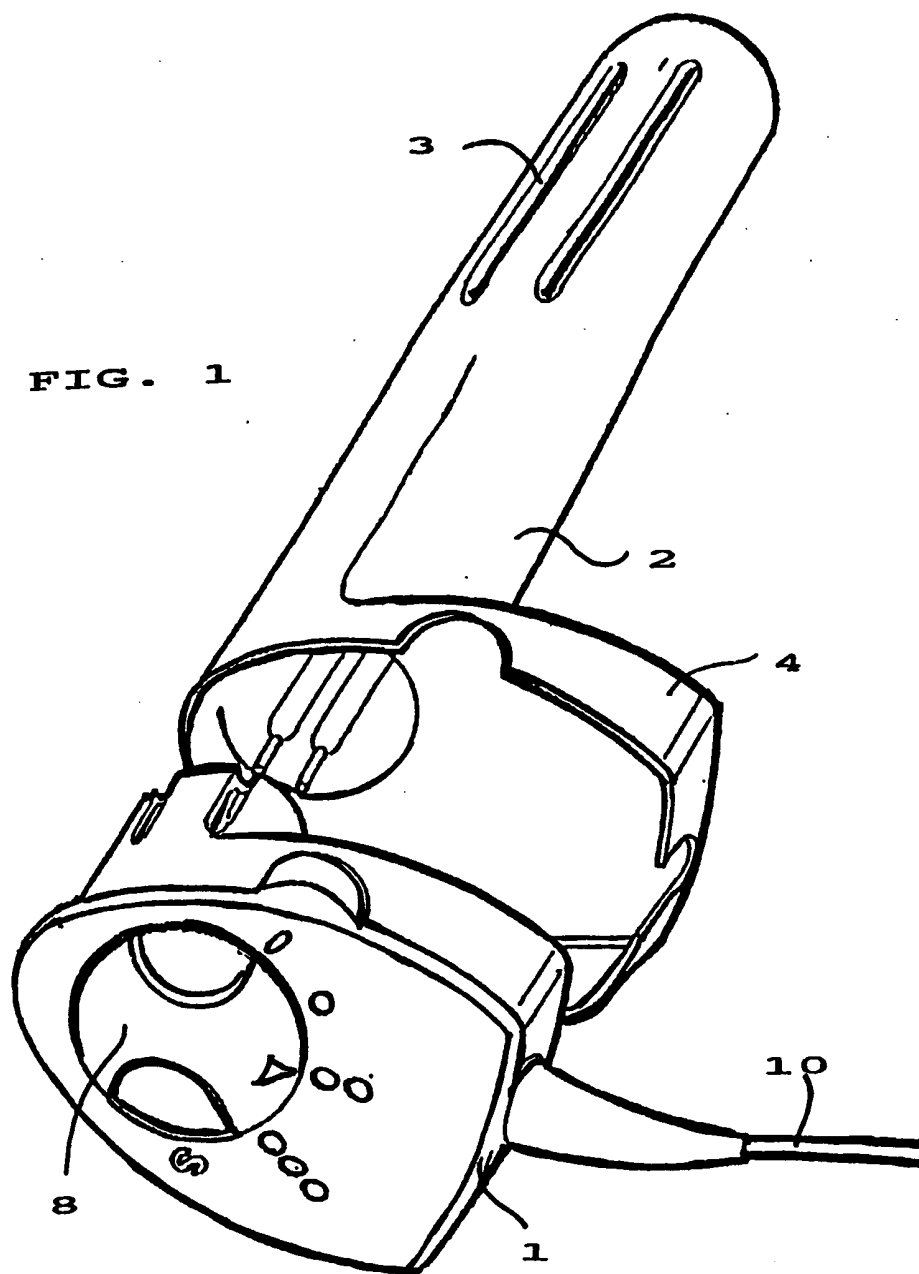
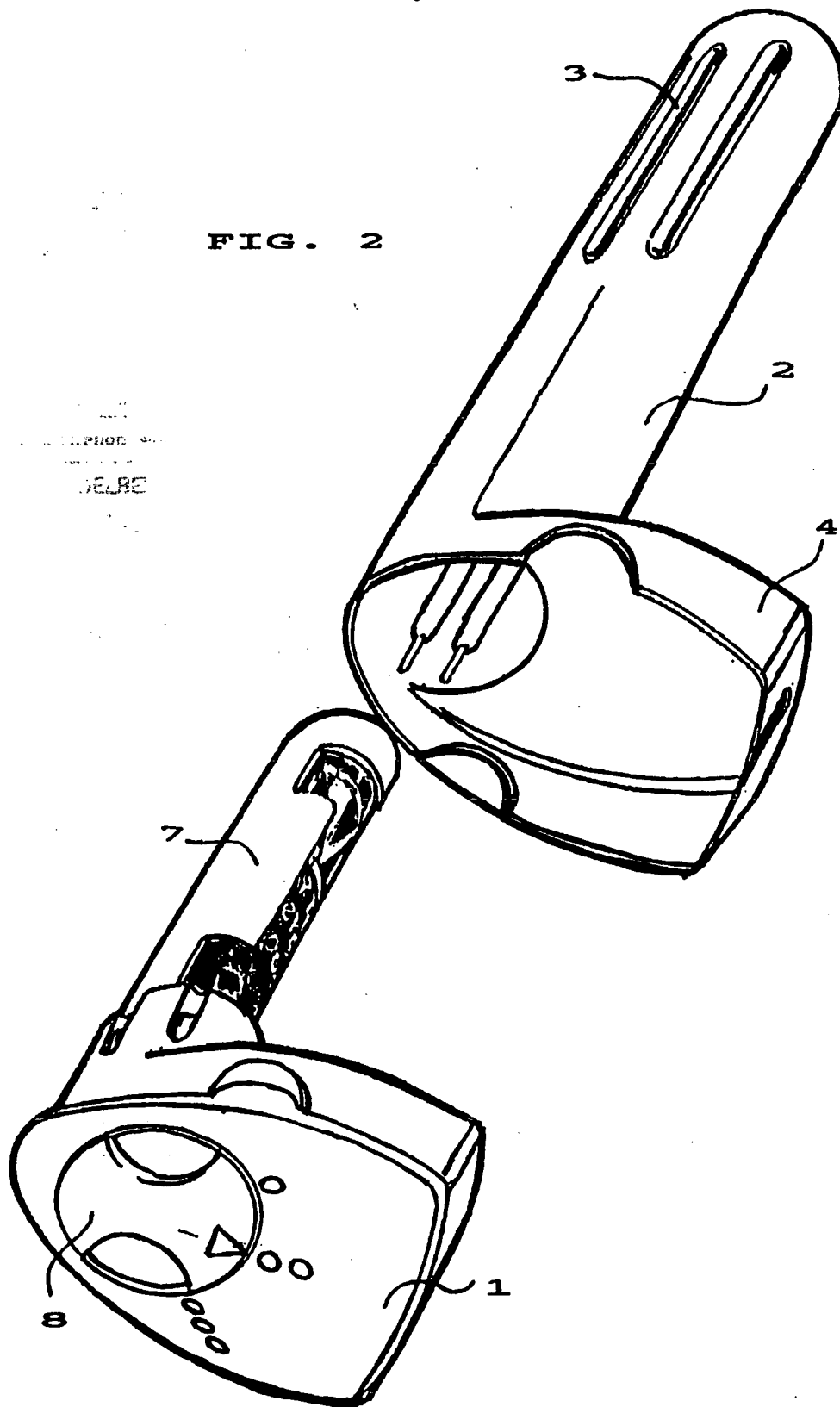


FIG. 2



3 / 3

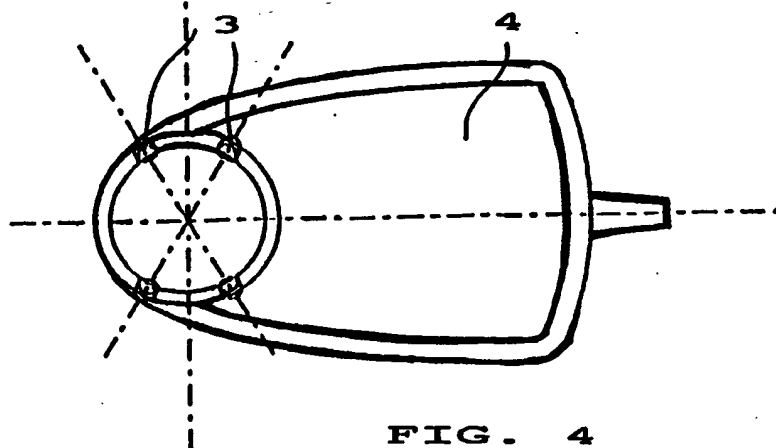
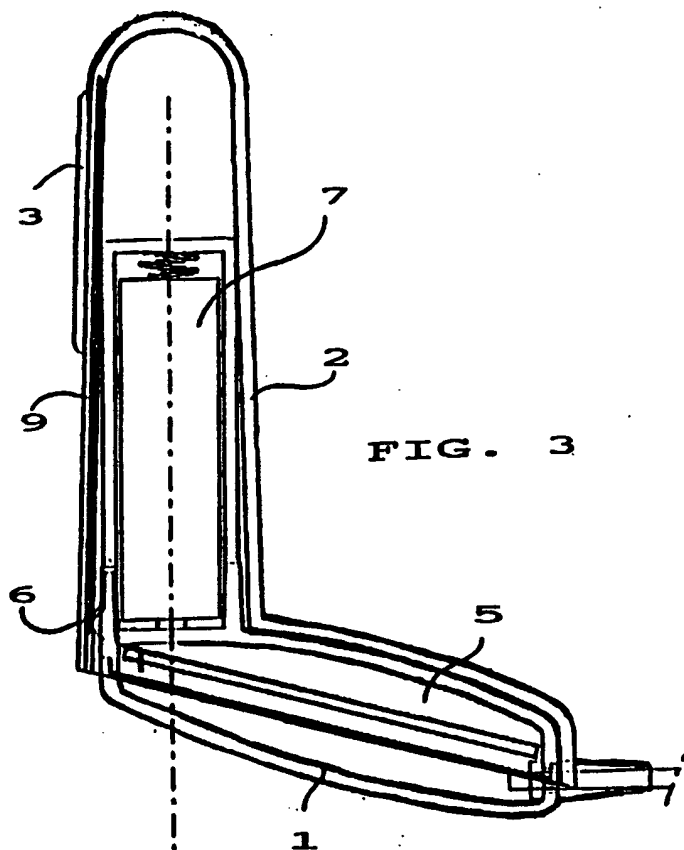


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 95/00087

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A63B 23/20, A61B 5/0488 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61B, A61N, A63B, G01L		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
WPI, CLAIMS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB, A, 2119516 (JOHN DELBERT PERRY), 16 November 1983 (16.11.83), page 3, line 105 - page 4, line 27, figures 1-3 --	1-10
X	DE, A1, 4038853 (STEINDORF, SUSANNE RUTH), 6 June 1991 (06.06.91), column 11, line 35 - line 53, figures 7-8, claims 7,15,19-21 --	1-5,7-10
X	WO, A1, 9317619 (PAUSER, ALEXANDER), 16 Sept 1993 (16.09.93), page 10, line 26 - page 11, line 2, figure 8 --	1-2
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "B" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
21 June 1995		26 -06- 1995
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Stefan Svahn Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 95/00087

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5154177 (EISMAN ET AL.), 13 October 1992 (13.10.92), column 3, line 21 - line 68, figure 1 --	1
E,X	WO, A1, 9415667 (CARMAN, BRENT), 21 July 1994 (21.07.94), abstract --	1,7,8,9
A	US, A, 4953563 (KAISER ET AL.), 4 Sept 1990 (04.09.90), abstract --	1-10
A	WO, A1, 9220283 (CARDIO DESIGN PTY LTD), 26 November 1992 (26.11.92), page 2, line 28 - page 3, line 11 -- -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

03/05/95

International application No.

PCT/FI 95/00087

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
GB-A-	2119516	16/11/83	NONE		
DE-A1-	4038853	06/06/91	DE-A-	4042434	26/03/92
WO-A1-	9317619	16/09/93	CA-A-	2102491	10/09/93
			EP-A-	0583456	23/02/94
			JP-T-	6507817	08/09/94
US-A-	5154177	13/10/92	NONE		
WO-A1-	9415667	21/07/94	NONE		
US-A-	4953563	04/09/90	NONE		
WO-A1-	9220283	26/11/92	NONE		

THIS PAGE BLANK (USPTO)